510(k) SUMMARY

Submitted by:

Cindy Foote
Regulatory Affairs Specialist
Cook Urological, Incorporated
1100 West Morgan Street
Spencer, Indiana 47460

OCT 27 2008

Device:

Trade Name: Cook Wire Guides

Proposed Classification Name: Endoscopic Guidewire, Gastroenterology-Urology
21 CFR Parts 876.1500
Class II, OCY

Predicate Devices:

The Cook Wire Guides are identical with respect to indications for use and technology to existing Cook Wire Guides currently on the market. Cook Wire Guides are identical with respect in technology to wire guides manufactured for Cook Urological, Incorporated by Cook Incorporated and Lake Region Manufacturing. The wire guide's marketed and distributed by Cook Incorporated have a different intended use than the wire guides' marketed and distributed by Cook Urological, Incorporated due to the different disciplines each of the companies represent.

Device Description:

Cook Wire Guides are designed to be used during Urological procedures where use of a wire guide is warranted. The wire guides consists of a single piece of wire tightly wound into coils from tip to tip. Two additional wires are present inside the coils, one called a flat safety wire and the other a round wire. Some of the wire guides are coated with a polymer sleeve, some with PTFE, some are stainless steel, and some are hydrophilically coated. Several variations of Cook Wire Guides are available. The wire guides are supplied sterile in peel-open packages and are intended for one-time use.

Substantial Equivalence:

The Cook Wire Guides are comparable with respect to intended use to the published predicate device description and meets the requirements for 510(k) substantial equivalence.

Test Data:

Biocompatibility, sterility and performance testing were performed in accordance to Food and Drug Administration guidance's and recognized international standards. Testing data and information are included in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2008

Ms. Cindy Foote
Regulatory Affairs Specialist
Cook Urological, Incorporated
1100 W. Morgan Street
SPENCER IN 47460

Re: K082536
Trade/Device Name: Cook Wire Guides
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCY
Dated: October 17, 2008
Received: October 22, 2008

Dear Ms. Foote:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K082536

Indications for Use

510(k) Number (if known): K082536

Cook Wire Guides:

Indications for Use: Cook Urological Wire Guides are used for ureteral access, to establish a tract, and assist in the placement, replacement, and exchange of devices during urological procedures. For the Roadrunner Wire Guides the intended use also includes use in a torturous or kinked ureter, traversing a large stone in route to the kidney, or in cases demanding enhanced control and high radiopacity. These wire guides are not intended for PTCA use.

Prescription Use? ___X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082536